# FGIS Process Verified Program
# Audit Report and Checklist

**Program:**
**Company:**
**Organizational Structure:**
**Contact and Title:**
**Location:**
**Email Address:**
**Audit Identifier:**
**Type of Audit:** Desk Audit
**Exempt Sections:** No If yes, which sections
**Lead Auditor:** Beth Hayden
**Auditor:** Beth Hayden
**Date:**
**Conclusion:** Request more information
**Audit Criteria:**

AUDIT ACTIVITIES:

| Section | Requirement | Identified Assigned | Responsibility Assigned | Implemented Maintained | Effective | Notes | Min. Maj. CIP |
|---|---|---|---|---|---|---|---|
| Element 4: QUALITY MANAGEMENT SYSTEM | | | | | | | |
| **4.1 General Requirements** (To be assessed at the end of the audit) | | | | | | | |
| 4.1 a | **The organization must:** identify the processes needed for the quality management system and their application throughout the organization | | | | | | |
| 4.1 b | determine the sequence and interaction of these processes | | | | | | |
| 4.1 c | determine criteria and methods needed to ensure that both the operation and control of these processes are effective | | | | | | |
| 4.1 d | Ensure the availability of resources and information necessary to support the operation and monitor these processes | | | | | | |
| 4.1 e | Monitor, measure and analyze these processes | | | | | | |
| 4.1 f | Implement actions necessary to achieve planned results and continual improvement of these processes | | | | | | |
| 4.1 g | Establish substantive, verifiable processes that add value to their product or service and substantiate marketing claims (Verification Points) | | | | | | |

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| **4.2 Documentation Requirements** | | | | | | | |
| 4.2 a | **The quality management system documentation must include:** a quality manual. | ☐ | ☐ | ☐ | ☐ | | ~~ |
| 4.2 b | documented statements of a quality policy and quality objectives. | ☐ | ☐ | ☐ | ☐ | | ~~ |
| 4.2 c | documented procedures required by this document. | ☐ | ☐ | ☐ | ☐ | | ~~ |
| 4.2 d | documents needed by the organization to ensure the effective planning, operation and control of its processes. | ☐ | ☐ | ☐ | ☐ | | ~~ |
| 4.2 e | records required by this document. | ☐ | ☐ | ☐ | ☐ | | ~~ |
| **4.2.2 Quality Manual** | | | | | | | |
| 4.2 a | **The organization must establish and maintain a quality manual that includes:** the scope of the process, including details of, and justification for, any exclusions. | ☐ | ☐ | ☐ | ☐ | | ~~ |
| 4.2 b | the specified process verification points | ☐ | ☐ | ☐ | ☐ | | ~~ |
| 4.2 c | the documented procedures established for the quality management system or reference to them | ☐ | ☐ | ☐ | ☐ | | ~~ |
| 4.2 d | a description of the interaction between the processes of the quality management system. | ☐ | ☐ | ☐ | ☐ | | ~~ |

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| 4.2 e | Other documents as required by the quality management system. | ☐ | ☐ | ☐ | ☐ | | ~~ |
| **4.2.3 Control of Documents** | | | | | | | |
| 4.2.3 | Documents required by the quality management system must be controlled. | ☐ | ☐ | ☐ | ☐ | | ~~ |
| 4.2.3 a | **A documented procedure must be established to define the controls needed to:** approve documents for adequacy prior to issue. | ☐ | ☐ | ☐ | ☐ | | ~~ |
| 4.2.3 b | to review and update, as necessary, and re-approve documents. | ☐ | ☐ | ☐ | ☐ | | ~~ |
| 4.2.3 c | ensure that changes and the current revision status of documents are identified. | ☐ | ☐ | ☐ | ☐ | | ~~ |
| 4.2.3 d | ensure that relevant versions of applicable documents are available at points of use. | ☐ | ☐ | ☐ | ☐ | | ~~ |
| 4.2.3 e | ensure that documents remain legible and readily identifiable. | ☐ | ☐ | ☐ | ☐ | | ~~ |
| 4.2.3 f | ensure that documents of external origin are identified and their distribution controlled. | ☐ | ☐ | ☐ | ☐ | ☐ | ~~ |
| 4.2.3 g | prevent the unintended use of obsolete documents, and to apply suitable identification to them if they are retained for any purpose. | ☐ | ☐ | ☐ | ☐ | | ~~ |
| **4.2.4 Control of records** | | | | | | | |
| 1.4 | Records must be | ☐ | ☐ | ☐ | ☐ | | ~~ |

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| | established and maintained to provide evidence of conformity to requirements and of the effective operation of the quality management system. | | | | | | |
| 1.4 | Records must remain legible, readily identifiable and retrievable. | ☐ | ☐ | ☐ | ☐ | | ~~ |
| 1.4 | A documented procedure must be established to define the controls needed for the identification, storage, protection, retrieval, retention time, and disposition of records. | ☐ | ☐ | ☐ | ☐ | | ~~ |
| Element 5: Management Responsibility | | | | | | | |
| **5.1 Management Commitment** | | | | | | | |
| 5.1 a | Top management must provide evidence of its commitment to the development and implementation of the quality management system and continually improve its effectiveness by communicating to the organization the importance of meeting customer, as well as statutory and regulatory, requirements. | ☐ | ☐ | ☐ | ☐ | | ~~ |
| 5.1 b | **Top management must provide evidence of its** | ☐ | ☐ | ☐ | ☐ | | ~~ |

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| | **commitment to the development and implementation of the quality management system and continually improve its effectiveness by:** establishing the quality policy. | | | | | | |
| 5 1 c | ensuring that quality objectives are established. | ☐ | ☐ | ☐ | ☐ | | ~~ |
| 5.1 d | conducting management reviews. | ☐ | ☐ | ☐ | ☐ | | ~~ |
| 5.1 e | its effectiveness by ensuring the availability of resources. | ☐ | ☐ | ☐ | ☐ | | ~~ |
| **5.2 Customer focus** | | | | | | | |
| 5.2 | Top management must ensure that customer requirements are determined and are met with the aim of enhancing customer satisfaction. | ☐ | ☐ | ☐ | ☐ | | ~~ |
| **2.3 Quality Policy** | | | | | | | |
| 5.3 a | **Top management must ensure that the quality policy:** is appropriate to the purpose of the organization. | ☐ | ☐ | ☐ | ☐ | | ~~ |
| 5.3 b | (Quality Policy) includes a commitment to comply with requirements and continually improve the effectiveness of the quality management system. | ☐ | ☐ | ☐ | ☐ | | ~~ |
| 5.3 c | provides a framework for establishing and reviewing quality | ☐ | ☐ | ☐ | ☐ | | ~~ |

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| | objectives. | | | | | | |
| 5.3 d | is communicated and understood within the organization. | ☐ | ☐ | ☐ | ☐ | | ~~ |
| 5.3 e | is reviewed for continuing suitability. | ☐ | ☐ | ☐ | ☐ | | ~~ |
| **5.4 Planning** | | | | | | | |
| **5.4.1 Quality Objectives** | | | | | | | |
| 5.4.1 | **Top management must ensure that quality objectives**, including those needed to meet requirements for product, are established at relevant functions and levels within the organization. | ☐ | ☐ | ☐ | ☐ | | ~~ |
| 5.4.1 | are measurable and consistent with the quality policy. | ☐ | ☐ | ☐ | ☐ | | ~~ |
| **5.4.2 Quality Management System Planning** | | | | | | | |
| 5.4.2.a | **Top management must ensure that the** planning of the quality management system is carried out in order to meet the general requirements of section 4 as well as the quality objectives. | ☐ | ☐ | ☐ | ☐ | | ~~ |
| 5.4.2.b | the integrity of the quality management system is maintained when changes to the quality management system are planned and implemented. | ☐ | ☐ | ☐ | ☐ | | ~~ |
| **5.5 Responsibility, authority and communication** | | | | | | | |
| **5.5.1 Responsibility and authority** | | | | | | | |

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| 5.5.1 | **Top management must ensure** that responsibilities and authorities are defined and communicated within the organization, including an organization chart or similar document listing all management personnel, their responsibilities and authorities. | ☐ | ☐ | ☐ | ☐ | | ~~ |
| **5.5.2 Management Representative** | | | | | | | |
| 5.5.2.a | **Top management must appoint a member of management who, irrespective of other responsibilities, has responsibility and authority that includes:** ensuring that processes needed for the quality management system are established, implemented, and maintained. | ☐ | ☐ | ☐ | ☐ | | ~~ |
| 5.5.2.b | reporting to top management on the performance of the quality management system and any need for improvement. | ☐ | ☐ | ☐ | ☐ | | ~~ |
| 5.5.2.c | ensuring the promotion of awareness of customer requirements throughout the organization. | ☐ | ☐ | ☐ | ☐ | | ~~ |
| **5.5.3 Internal Communication** | | | | | | | |
| 5.5.3 | **Top management** | ☐ | ☐ | ☐ | ☐ | | ~~ |

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| | **must:** ensure that appropriate communication processes are established within the organization and that communication takes place regarding the effectiveness of the quality management system. | | | | | | |
| **5.6 Management Review** | | | | | | | |
| **5.6.1 General** | | | | | | | |
| 5.6.1 | review the organization's quality management system, at planned intervals, to ensure its continuing suitability, adequacy, and effectiveness. | ☐ | ☐ | ☐ | ☐ | | ~~ |
| 5.6.1 | This review must include assessing opportunities for improvement and the need for changes to the quality management system, including the quality policy and quality objectives. | ☐ | ☐ | ☐ | ☐ | | ~~ |
| 5.6.1 | Records from management reviews must be maintained. | ☐ | ☐ | ☐ | ☐ | | ~~ |
| **5.6.2 Review Input** | | | | | | | |
| 5.6.2.a | **The input to management reviews must include: information on:** results of audits. | ☐ | ☐ | ☐ | ☐ | | ~~ |
| 5.6.2.b | customer feedback. | ☐ | ☐ | ☐ | ☐ | | ~~ |
| 5.6.2.c | process performance and product | ☐ | ☐ | ☐ | ☐ | | ~~ |

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| | conformity. | | | | | | |
| 5.6.2.d | status of preventive and corrective actions. | ☐ | ☐ | ☐ | ☐ | | ~~ |
| 5.6.2.e | follow up actions from previous management reviews. | ☐ | ☐ | ☐ | ☐ | | ~~ |
| 5.6.2.f | changes that could affect the quality management system. | ☐ | ☐ | ☐ | ☐ | | ~~ |
| 5.6.2.g | recommendations for improvement. | ☐ | ☐ | ☐ | ☐ | | ~~ |
| **5.6.3 Review Output** | | | | | | | |
| 5.6.3.a | **The output from the management review must include any decisions and actions related to** improvement of the effectiveness of the quality management system and its processes. | ☐ | ☐ | ☐ | ☐ | | ~~ |
| 5.6.3.b | improvement of product related to customer requirements. | ☐ | ☐ | ☐ | ☐ | | ~~ |
| 5.6.3.c | resources needs. | ☐ | ☐ | ☐ | ☐ | | ~~ |
| Element 6: Resource Management | | | | | | | |
| **6.1 Provision of resources** | | | | | | | |
| 6.1 | **The organization must determine and provide the resources needed to** implement and maintain the quality management system and continually improve its effectiveness. | ☐ | ☐ | ☐ | ☐ | | ~~ |
| 6.1 | enhance customer satisfaction by meeting customer requirements. | ☐ | ☐ | ☐ | ☐ | | ~~ |

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| **6.2 Human Resources** | | | | | | | |
| **6.2.1. General** | | | | | | | |
| 6.2.1 | Personnel performing work affecting product quality must be competent on the basis of appropriate education, training, skills, and experience. | ☐ | ☐ | ☐ | ☐ | | ~~ |
| **6.2.2 Competence, Awareness and Training** | | | | | | | |
| 6.2.2 a | **The organization must document a procedure to**: determine the necessary competence for personnel performing work affecting product quality. | ☐ | ☐ | ☐ | ☐ | | ~~ |
| 6.2.2 b | provide training or take other actions to satisfy these needs. | ☐ | ☐ | ☐ | ☐ | | ~~ |
| 6.2.2 c | evaluate the effectiveness of the actions taken. | ☐ | ☐ | ☐ | ☐ | | ~~ |
| 6.2.2 d | ensure that its personnel are aware of the relevance and importance of their activities and how they contribute to the achievement of the quality objectives. | ☐ | ☐ | ☐ | ☐ | | ~~ |
| 6.2.2 e | maintenance of appropriate records of education, training, skills, and experience. | ☐ | ☐ | ☐ | ☐ | | ~~ |
| **6.3 Infrastructure** | | | | | | | |
| 6.3 a | **The organization must** determine, | ☐ | ☐ | ☐ | ☐ | | ~~ |

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| | provide, and maintain the infrastructure needed to achieve conformity to product requirements. Infrastructure includes, as applicable, buildings, workspace, and associated utilities, process equipment (both hardware and software), and supporting services (such as, transport or communication). | | | | | | |
| **6.4 Work environment** | | | | | | | |
| 6.4. | determine and manage the work environment needed to achieve conformity to product requirements. | ☐ | ☐ | ☐ | ☐ | | ~~ |
| Element 7: Product Realization | | | | | | | |
| **7.1 Planning of product realization** | | | | | | | |
| 7.1 | The organization must plan and develop the processes needed for product realization. Planning of product realization must be consistent with the other processes of the quality management system. | ☐ | ☐ | ☐ | ☐ | | ~~ |
| 7.1.1.a | **In planning product realization, the organization must determine the following, as appropriate**, quality | ☐ | ☐ | ☐ | ☐ | | ~~ |

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| | objectives and requirements for the product. | | | | | | |
| 7.1.1.b | the need to establish processes, documents, and provide resources specific to the product. | ☐ | ☐ | ☐ | ☐ | | ~~ |
| 7.1.1.c | required verification, validation, monitoring, inspection, and test activities specific to the product and the criteria for product acceptance. | ☐ | ☐ | ☐ | ☐ | | ~~ |
| 7.1.1.d | records needed to provide evidence that the realization processes and resulting product meet requirements. | ☐ | ☐ | ☐ | ☐ | | ~~ |
| 7.1.2 | The output of this planning must be in a form suitable for the organization's method of operations. | ☐ | ☐ | ☐ | ☐ | | ~~ |
| **7.2 Customer-related processes** | | | | | | | |
| **7.2.1 Determination of requirements related to the product** | | | | | | | |
| 7.2.1.a | The organization must determine requirements specified by the customer, including the requirements for delivery and post-delivery activities. | ☐ | ☐ | ☐ | ☐ | | ~~ |
| 7.2.1.b | **The organization must determine** requirements not stated by the customer, but necessary for specified or intended use, where known. | ☐ | ☐ | ☐ | ☐ | | ~~ |
| 7.2.1.c | statutory and regulatory | ☐ | ☐ | ☐ | ☐ | | ~~ |

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| | requirements related to the product. | | | | | | |
| 7.2.1.d | any additional requirements determined by the organization. | ☐ | ☐ | ☐ | ☐ | | ~~ |
| **7.2.2 Review of Requirements Related to the Product** | | | | | | | |
| 7.2.2.a | The organization must review the requirements related to the product. **This review must be conducted prior to the organization's commitment to supply the product to the customer and ensure that** product requirements are defined. | ☐ | ☐ | ☐ | ☐ | | ~~ |
| 7.2.2.b | contract or order requirements differing from those previously expressed are resolved. | ☐ | ☐ | ☐ | ☐ | | ~~ |
| 7.2.2.c | the organization has the ability to meet the defined requirements. | ☐ | ☐ | ☐ | ☐ | | ~~ |
| 7.2.2 | Records of the results of the review and actions arising from the review are maintained. | ☐ | ☐ | ☐ | ☐ | | ~~ |
| 7.2.2 | Where the customer provides no documented statement of requirements, the customer requirements must be confirmed by the organization before acceptance. | ☐ | ☐ | ☐ | ☐ | | ~~ |
| 7.2.2 | Where product requirements are | ☐ | ☐ | ☐ | ☐ | | ~~ |

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| | changed, the organization must ensure that relevant documents are amended and that relevant personnel are made aware of the changed requirements. | | | | | | |
| **7.2.3 Customer Communication** | | | | | | | |
| 7.2.3.a | **The organization must determine and implement effective arrangements for communicating with customers in relation to** product information. | ☐ | ☐ | ☐ | ☐ | | ~~ |
| 7.2.3.b | inquiries, contracts or order handling, including amendments. | ☐ | ☐ | ☐ | ☐ | | ~~ |
| 7.2.3.c | customer feedback, including customer complaints. | ☐ | ☐ | ☐ | ☐ | | ~~ |
| **7.3 Design and development** | | | | | | | |
| **7.3.1 Design and development planning** | | | | | | | |
| 7.3.1 | The organization must plan and control the design and development of product. | ☐ | ☐ | ☐ | ☐ | | ~~ |
| 7.3.1.a | **During the design and development planning, the organization must** determine the design and development stages. | ☐ | ☐ | ☐ | ☐ | | ~~ |
| 7.3.1.b | determine the review certification and validation that are appropriate to each design and | ☐ | ☐ | ☐ | ☐ | | ~~ |

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| | development stage. | | | | | | |
| 7.3.1.c | determine the responsibilities and authorities for design and development. | ☐ | ☐ | ☐ | ☐ | | ~~ |
| 7.3.1 | The organization must manage the interfaces between the different groups involved in design and development to ensure effective communication and clear assignment of responsibility. | ☐ | ☐ | ☐ | ☐ | | ~~ |
| 7.3.1 | Planning output must be updated, as appropriate, as the design and development progresses. | ☐ | ☐ | ☐ | ☐ | | ~~ |
| **7.3.2 Design and Development Inputs** | | | | | | | |
| 7.3.2 | Inputs relating to product requirements must be determined and records maintained. | ☐ | ☐ | ☐ | ☐ | | ~~ |
| 7.3.2.a | **These inputs must include:** functional and performance requirements. | ☐ | ☐ | ☐ | ☐ | | ~~ |
| 7.3.2.b | applicable statutory and regulatory requirements. | ☐ | ☐ | ☐ | ☐ | | ~~ |
| 7.3.2.c | where applicable, information derived from previous similar designs. | ☐ | ☐ | ☐ | ☐ | | ~~ |
| 7.3.2.d | other requirements essential for design and development. | ☐ | ☐ | ☐ | ☐ | | ~~ |

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| 7.3.2 | These inputs must be reviewed for adequacy. | ☐ | ☐ | ☐ | ☐ | | ~~ |
| 7.3.2 | Requirements must be complete, unambiguous, and not in conflict with each other. | ☐ | ☐ | ☐ | ☐ | | ~~ |
| **7.3.3 Design and Development Outputs** | | | | | | | |
| 7.3.3 | The outputs of design and development must be provided in a form that enables verification against the design and development input and must be approved prior to release. | ☐ | ☐ | ☐ | ☐ | | ~~ |
| 7.3.3.a | **Design and development outputs must:** meet input requirements for design development. | ☐ | ☐ | ☐ | ☐ | | ~~ |
| 7.3.3.b | provide appropriate information for purchasing, production, and for service provision. | ☐ | ☐ | ☐ | ☐ | | ~~ |
| 7.3.3.c | contain or reference product acceptance criteria. | ☐ | ☐ | ☐ | ☐ | | ~~ |
| 7.3.3.d | specify the characteristics of the product that are essential for its safe and proper use. | ☐ | ☐ | ☐ | ☐ | | ~~ |
| **7.3.4 Design and Development Review** | | | | | | | |
| 7.3.4.a | **At suitable stages, systematic reviews of design and development must be performed in** | ☐ | ☐ | ☐ | ☐ | | ~~ |

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| | **accordance with planned arrangements (see 7.3.1)** to evaluate the ability of the results of design and development to meet requirements. | | | | | | |
| 7.3.4.b | to identify any problems and propose necessary actions. | ☐ | ☐ | ☐ | ☐ | | ~~ |
| 7.3.4 | Participants in such reviews must include representatives of functions concerned with the design and development stage(s) being reviewed. | ☐ | ☐ | ☐ | ☐ | | ~~ |
| 7.3.4 | Records of the results of the reviews and any necessary actions must be maintained. | ☐ | ☐ | ☐ | ☐ | | ~~ |
| **7.3.5 Design and Development Verification** | | | | | | | |
| 7.3.5 | Verification must be performed in accordance with planned arrangements to ensure that the design and development outputs have met the design and development input requirements. | ☐ | ☐ | ☐ | ☐ | | ~~ |
| 7.3.5 | Records of the results of the verification and any necessary actions must be maintained. | ☐ | ☐ | ☐ | ☐ | | ~~ |
| **7.3.6 Design and Development Validation** | | | | | | | |
| 7.3.6 | Design and development validation must be performed in | ☐ | ☐ | ☐ | ☐ | | ~~ |

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| | accordance with planned arrangements to ensure that the resulting product is capable of meeting the requirements for the specified application or intended use, where known. | | | | | | |
| 7.3.6 | Wherever practical, validation must be completed prior to delivery or implementation of the product. | ☐ | ☐ | ☐ | ☐ | | ~~ |
| 7.3.6 | Records of the results of validation and any necessary actions must be maintained. | ☐ | ☐ | ☐ | ☐ | | ~~ |
| **7.3.7 Control of Design and Development Changes** | | | | | | | |
| 7.3.7 | Design and development changes must be identified and records maintained. | ☐ | ☐ | ☐ | ☐ | | ~~ |
| 7.3.7 | The changes must be reviewed, verified, validated, as appropriate, and approved before implementation. | ☐ | ☐ | ☐ | ☐ | | ~~ |
| 7.3.7 | The review of design and development changes must include evaluation of the effect of the changes on the constituent parts and product already delivered. | ☐ | ☐ | ☐ | ☐ | | ~~ |
| 7.3.7 | Records of the results of the review of | ☐ | ☐ | ☐ | ☐ | | ~~ |

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| | changes and any necessary actions must be maintained see. | | | | | | |
| **7.4 Purchasing Process** | | | | | | | |
| 7.4. | Where an organization out sources any of its processes, supplies, ingredients or services, it must identify them and specify how it plans to control the items or activities. | ☐ | ☐ | ☐ | ☐ | | ~~ |
| 7.4.1 | The organization must ensure that purchased product or product received from an outside establishment conforms to specified purchase requirements. The type and extent of control applied to the supplier and the purchased product must be dependent on the effect of the purchased product on subsequent product realization or the final product. | ☐ | ☐ | ☐ | ☐ | | ~~ |
| 7.4.1 | The organization must evaluate and select suppliers based on their ability to supply product in accordance with the organization's requirements. | ☐ | ☐ | ☐ | ☐ | | ~~ |
| 7.4.1 | Criteria for selection, evaluation, and re-evaluation must be established. | ☐ | ☐ | ☐ | ☐ | | ~~ |
| 7.4.1 | Records of the results | ☐ | ☐ | ☐ | ☐ | | ~~ |

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| | of evaluations and any necessary actions arising from the evaluation must be maintained. | | | | | | |
| **7.4.2 Purchasing Information** | | | | | | | |
| 7.4.2.a | **Purchasing information must describe product to be purchased or received, including, where appropriate, requirements for** approval of product, procedures, processes and equipment. | ☐ | ☐ | ☐ | ☐ | | ~~ |
| 7.4.2.b | qualifications of personnel. | ☐ | ☐ | ☐ | ☐ | | ~~ |
| 7.4.2.c | quality system requirements. | ☐ | ☐ | ☐ | ☐ | | ~~ |
| 7.4.2 | The organization must ensure the adequacy of specified purchase requirements prior to their communication to the supplier. | ☐ | ☐ | ☐ | ☐ | | ~~ |
| **7.4.3 Verification of Purchased Product** | | | | | | | |
| 7.4.3 | The organization must establish and implement the inspection or other activities necessary for ensuring that purchased product meets specified purchase requirements. | ☐ | ☐ | ☐ | ☐ | | ~~ |
| 7.4.3 | Where the organization or its customer intends to perform verification at the supplier's premises, the organiz-ation must state the | ☐ | ☐ | ☐ | ☐ | | ~~ |

| Section | Requirement | Identified Assigned | Responsibility Assigned | Implemented Maintained | Effective | Notes | Min. Maj. CIP |
|---|---|---|---|---|---|---|---|
| | intended verification arrangements and method of product release in the purchasing information. | | | | | | |
| 7.4.4 a | **The organization must have a documented procedure addressing the following**: all products or services received from outside establishments that affect the quality management system or product. | ☐ | ☐ | ☐ | ☐ | | ~~ |
| 7.4.4 b | the receiving requirements for approval of products to be used in the product. | ☐ | ☐ | ☐ | ☐ | | ~~ |
| 7.4.4 c | the criteria and process for selection, evaluation and re-evaluation of the supplier. | ☐ | ☐ | ☐ | ☐ | | ~~ |
| 7.4.4 d | the process used to ensure that products or services purchased or received from outside establishments and used in the product conform to specific requirements. | ☐ | ☐ | ☐ | ☐ | | ~~ |
| **7.5 Production and Service Provision** | | | | | | | |
| **7.5.1 Control of Production and Service Provision** | | | | | | | |
| 7.5.1 | The organization must plan and carry out production and service provision under controlled conditions. | ☐ | ☐ | ☐ | ☐ | | ~~ |

| Section | Requirement | Identified Assigned | Responsibility Assigned | Implemented Maintained | Effective | Notes | Min. Maj. CIP |
|---|---|---|---|---|---|---|---|
| 7.5.1.a | **Controlled conditions must include, as applicable**, the availability of information that describes the characteristics of the product. | ☐ | ☐ | ☐ | ☐ | | ~~ |
| 7.5.1.b | the availability of work instructions, as necessary. | ☐ | ☐ | ☐ | ☐ | | ~~ |
| 7.5.1.c | the use of suitable equipment | ☐ | ☐ | ☐ | ☐ | | ~~ |
| 7.5.1.d | the availability and use of monitoring and measuring devices. | ☐ | ☐ | ☐ | ☐ | | ~~ |
| 7.5.1.e | implementation of monitoring and measurement. | ☐ | ☐ | ☐ | ☐ | | ~~ |
| 7.5.1.f | the implementation of release, delivery, and post-delivery activities. | ☐ | ☐ | ☐ | ☐ | | ~~ |
| **7.5.2 Validation of Processes for Production and Service Provision** | | | | | | | |
| 7.5.2 | The organization must validate any processes for production and service provision where the resulting output cannot be verified by subsequent monitoring or measurement. This includes any processes where deficiencies become apparent only after the product is in use or the service has been delivered. | ☐ | ☐ | ☐ | ☐ | | ~~ |
| 7.5.2 | Validation must demonstrate the ability of these processes to achieve planned results. | ☐ | ☐ | ☐ | ☐ | | ~~ |

| Section | Requirement | Identified Assigned | Responsibility Assigned | Implemented Maintained | Effective | Notes | Min. Maj. CIP |
|---|---|---|---|---|---|---|---|
| 7.5.2.a | **The organization must establish arrangements for these processes including, as applicable,** defined criteria for review and approval of the processes. | ☐ | ☐ | ☐ | ☐ | | ~~ |
| 7.5.2.b | approval of equipment and qualification of personnel. | ☐ | ☐ | ☐ | ☐ | | ~~ |
| 7.5.2.c | use of specific methods and procedures. | ☐ | ☐ | ☐ | ☐ | | ~~ |
| 7.5.2.d | requirements for records. | ☐ | ☐ | ☐ | ☐ | | ~~ |
| 7.5.2.e | revalidation. | ☐ | ☐ | ☐ | ☐ | | ~~ |
| **7.5.3 Identification and Tracking** | | | | | | | |
| 7.5.3 a | **The organization must have a documented procedure to**: identify the product by suitable means throughout the product realization, where appropriate. | ☐ | ☐ | ☐ | ☐ | | ~~ |
| 7.5.3 b | identify the product status with respect to monitoring and measurement requirements. | ☐ | ☐ | ☐ | ☐ | | ~~ |
| 7.5.3 c | control and record the unique identification of the product, when tracking is a requirement. | ☐ | ☐ | ☐ | ☐ | | ~~ |
| 7.5.3 d | control and record the use of the “USDA Process Verified: shield or the term “USDA | ☐ | ☐ | ☐ | ☐ | | ~~ |

| Section | Requirement | Identified Assigned | Responsibility Assigned | Implemented Maintained | Effective | Notes | Min. Maj. CIP |
|---|---|---|---|---|---|---|---|
| | Process Verified", if applicable. | | | | | | |
| **7.5.4 Customer Property** | | | | | | | |
| 7.5.4 | The organization must exercise care with customer property, including intellectual property, while it is under the organization's control or being used by the organization. The organization must identify, verify, protect, and safeguard customer property provided for use or incorporation into the product. | ☐ | ☐ | ☐ | ☐ | | ~~ |
| 7.5.4 | If any customer property is lost, damaged, or otherwise found to be unsuitable for use, this must be reported to the customer and records maintained. | ☐ | ☐ | ☐ | ☐ | | ~~ |
| **7.5.5 Preservation of product.** | | | | | | | |
| 7.5.5 | The organization must preserve the conformity of product during internal processing and delivery to the intended destination. | ☐ | ☐ | ☐ | ☐ | | ~~ |
| 7.5.5 | This preservation must include identification, handling, packaging, storage, and protection. | ☐ | ☐ | ☐ | ☐ | | ~~ |
| 7.5.5 | Preservation must also apply to the constituent parts of a product. | ☐ | ☐ | ☐ | ☐ | | ~~ |
| **7.6 Control of Monitoring and Measuring Devices** | | | | | | | |
| 7.6.1 | **The organization** | ☐ | ☐ | ☐ | ☐ | | ~~ |

| Section | Requirement | Identified Assigned | Responsibility Assigned | Implemented Maintained | Effective | Notes | Min. Maj. CIP |
|---|---|---|---|---|---|---|---|
| | **must** determine monitoring and measurement to be undertaken and the monitoring and measuring devices needed to provide evidence of conformity of product to deter-mined requirements. | | | | | | |
| 7.6.2 | establish processes to ensure that monitoring and measurement can be carried out and are carried out in a manner that is consistent with the monitoring and measurement requirements. | ☐ | ☐ | ☐ | ☐ | | ~~ |
| 7.6.3.a | **Where necessary to ensure valid results, measuring equipment must be** calibrated or verified at specified intervals, or prior to use, against measurement standards traceable to international or national measurement standards: Where no such standards exist, the basis used for calibration or verification must be recorded. | ☐ | ☐ | ☐ | ☐ | | ~~ |
| 7.6.3.b | adjusted or re-adjusted as necessary. | ☐ | ☐ | ☐ | ☐ | | ~~ |
| 7.6.3.c | identified to enable the calibration status to be determined. | ☐ | ☐ | ☐ | ☐ | | ~~ |

| Section | Requirement | Identified Assigned | Responsibility Assigned | Implemented Maintained | Effective | Notes | Min. Maj. CIP |
|---|---|---|---|---|---|---|---|
| 7.6.3.d | safeguarded from adjustments that would invalidate the measurement results. | ☐ | ☐ | ☐ | ☐ | | ~~ |
| 7.6.3.e | protected from damage and deterioration during handling, maintenance, and storage. | ☐ | ☐ | ☐ | ☐ | | ~~ |
| 7.6.4 | In addition, the organization must assess and record the validity of the previous measuring results when the equipment is found not to conform to requirements. | ☐ | ☐ | ☐ | ☐ | | ~~ |
| 7.6.4 | The organization must take appropriate action on the equipment and any product affected. | ☐ | ☐ | ☐ | ☐ | | ~~ |
| 7.6.4 | Records of the results of calibration and verification must be maintained. | ☐ | ☐ | ☐ | ☐ | | ~~ |
| 7.6.5 | When used in the monitoring and measurement of specified requirements, the ability of computer software to satisfy the intended application must be confirmed. This must be undertaken prior to initial use and reconfirmed as necessary. | ☐ | ☐ | ☐ | ☐ | | ~~ |
| Element 8: Measurement, Analysis and Improvement | | | | | | | |
| **8.1 General** | | | | | | | |

| Section | Requirement | Identified Assigned | Responsibility Assigned | Implemented Maintained | Effective | Notes | Min. Maj. CIP |
|---|---|---|---|---|---|---|---|
| 8.1.a | **The organization must plan and implement the monitoring, measurement, analysis, and improvement processes needed to** demonstrate conformity of product. | ☐ | ☐ | ☐ | ☐ | | ~~ |
| 8.1.b | ensure conformity of the quality process system. | ☐ | ☐ | ☐ | ☐ | | ~~ |
| 8.1.c | continually improve the effectiveness of the quality management system. | ☐ | ☐ | ☐ | ☐ | | ~~ |
| 8.1 | This must include determination of applicable methods, including statistical techniques, and the extent of their use. | ☐ | ☐ | ☐ | ☐ | | ~~ |
| **8.2.1 Customer Satisfaction** | | | | | | | |
| 8.2.1 | As one of the measurements of the performance of the quality process system, the organization must monitor information relating to customer perception as to whether the organization has met customer requirements. The methods for obtaining and using this information must be determined. | ☐ | ☐ | ☐ | ☐ | | ~~ |
| **8.2.1** | The organization must take appropriate actions | ☐ | ☐ | ☐ | ☐ | | ~~ |

| Section | Requirement | Identified Assigned | Responsibility Assigned | Implemented Maintained | Effective | Notes | Min. Maj. CIP |
|---|---|---|---|---|---|---|---|
| | to address customer complaints regarding conformance to the quality management system or the resulting products or service. | | | | | | |
| **8.2.1** | Records of customer complaints and any actions taken to address them must be maintained. | ☐ | ☐ | ☐ | ☐ | | ~~ |
| **8.2.2 Internal Audits** | | | | | | | |
| 8.2.2 | **The organization must conduct internal audits at planned intervals to determine whether the quality management system** conforms to the planned arrangements, to the general requirements, and to the quality management system requirements established by the organization, and is effectively implemented and maintained. | ☐ | ☐ | ☐ | ☐ | | ~~ |
| 8.2.2 a | The organization must have a documented procedure which addresses planning the audit program taking into consideration the status and importance of the processes and areas to be audited, as well as the results of previous audits. | ☐ | ☐ | ☐ | ☐ | | ~~ |

| Section | Requirement | Identified Assigned | Responsibility Assigned | Implemented Maintained | Effective | Notes | Min. Maj. CIP |
|---|---|---|---|---|---|---|---|
| 8.2.2 b | Audit criteria, scope, frequency, and methods used | ☐ | ☐ | ☐ | ☐ | | ~~ |
| 8.2.2 c | Selection of auditors and conduct of audits must ensure objectivity and impartiality of the audit process. Auditors must not audit their own work. | ☐ | ☐ | ☐ | ☐ | | ~~ |
| 8.2.2 d | The responsibilities and requirements for planning and conducting audits | ☐ | ☐ | ☐ | ☐ | | ~~ |
| 8.2.2 e | Reporting audit results | ☐ | ☐ | ☐ | ☐ | | ~~ |
| 8.2.2 f | following up on activities, including the verification of actions taken and the reporting of the verification results; and | ☐ | ☐ | ☐ | ☐ | | ~~ |
| 8.2.2 g | Maintaining records | ☐ | ☐ | ☐ | ☐ | | ~~ |
| 8.2.2 | Management responsible for the area being audited must ensure that actions are taken without undue delay to eliminate detected nonconformities and their causes | ☐ | ☐ | ☐ | ☐ | | ~~ |
| **8.2.3 Monitoring and Measurement of Processes** | | | | | | | |
| 8.2.3 | The organization must apply suitable methods for monitoring and, where applicable, measurement of quality system processes. | ☐ | ☐ | ☐ | ☐ | | ~~ |
| 8.2.3 | These methods must demonstrate the ability of the processes to | ☐ | ☐ | ☐ | ☐ | | ~~ |

| Section | Requirement | Identified Assigned | Responsibility Assigned | Implemented Maintained | Effective | Notes | Min. Maj. CIP |
|---|---|---|---|---|---|---|---|
| | achieve planned results. | | | | | | |
| 8.2.3 | When planned results are not achieved, correction and corrective action must be taken, as appropriate, to ensure conformity of the product. | ☐ | ☐ | ☐ | ☐ | | ~~ |
| **8.2.4 Monitoring and Measurement of Product** | | | | | | | |
| 8.2.4 | The organization must monitor and measure the characteristics of the product to verify that product requirements have been met. This must be carried out at appropriate stages of the product realization process in accordance with the planned arrangements. | ☐ | ☐ | ☐ | ☐ | | ~~ |
| 8.2.4 | Evidence of conformity with the acceptance criteria must be maintained. Records must indicate the person(s) authorizing release of product. | ☐ | ☐ | ☐ | ☐ | | ~~ |
| 8.2.4 | Product release and service delivery must not proceed until the planned arrangements have been satisfactorily completed, unless otherwise approved by a relevant authority and, where applicable, by the customer. | ☐ | ☐ | ☐ | ☐ | | ~~ |
| **8.3 Control of Nonconforming Product** | | | | | | | |

| Section | Requirement | Identified Assigned | Responsibility Assigned | Implemented Maintained | Effective | Notes | Min. Maj. CIP |
|---|---|---|---|---|---|---|---|
| 8.3.1 | The organization must ensure that product that does not conform to product requirements is identified and controlled to prevent its unintended use or delivery. The identification of non-conforming product, the controls used to prevent the unintended use or delivery of non-conforming product, and the related responsibilities and authorities for dealing with nonconforming product must be defined in a documented procedure. | ☐ | ☐ | ☐ | ☐ | | ~~ |
| 8.3.2 | The organization must deal with nonconforming product by one or more of the following ways:<br><br>a) By taking action to eliminate the detected nonconformity;<br><br>b) by authorizing its use, release or acceptance under concession by a relevant authority and, where applicable, by the customer;<br><br>c) by taking action to preclude its original | ☐ | ☐ | ☐ | ☐ | | ~~ |

| Section | Requirement | Identified Assigned | Responsibility Assigned | Implemented Maintained | Effective | Notes | Min. Maj. CIP |
|---|---|---|---|---|---|---|---|
| | intended use or application. | | | | | | |
| 8.3.3 | Records of the nature of nonconformities and any subsequent actions taken, including concessions obtained, must be maintained. | ☐ | ☐ | ☐ | ☐ | | ~~ |
| 8.3.4 | When nonconforming product is corrected, it must be subject to re-verification to demonstrate conformity to the requirements. | ☐ | ☐ | ☐ | ☐ | | ~~ |
| 8.3.5 | When nonconforming product is detected after delivery or use has started, the organization must take action appropriate to the effects, or potential effects, of the nonconformity. | ☐ | ☐ | ☐ | ☐ | | ~~ |
| **8.4 Analysis of Data** | | | | | | | |
| 8.4 | The organization must determine, collect, and analyze appropriate data to demonstrate the suitability and effectiveness of the quality management system and to evaluate where continual improvement of the effectiveness of the system can be made. This must include data generated as a result of | ☐ | ☐ | ☐ | ☐ | | ~~ |

| Section | Requirement | Identified Assigned | Responsibility Assigned | Implemented Maintained | Effective | Notes | Min. Maj. CIP |
|---|---|---|---|---|---|---|---|
| | monitoring and measurement and from other relevant sources. | | | | | | |
| 8.4.a | **The analysis of data must provide information relating to** customer satisfaction. | ☐ | ☐ | ☐ | ☐ | | ~~ |
| 8.4.b | conformity to product requirements. | ☐ | ☐ | ☐ | ☐ | | ~~ |
| 8.4.c | characteristics and trends of processes and products including opportunities for preventive action. | ☐ | ☐ | ☐ | ☐ | | ~~ |
| 8.4.d | suppliers. | ☐ | ☐ | ☐ | ☐ | | ~~ |
| **8.5 Improvement** | | | | | | | |
| **8.5.1 Continual Improvement** | | | | | | | |
| 8.5.1 | The organization must continually improve the effectiveness of the quality management system through the use of the quality policy, quality objectives, audit results, analysis of data, corrective and preventive actions, and management review. | ☐ | ☐ | ☐ | ☐ | | ~~ |
| **8.5.2 Corrective Action** | | | | | | | |
| 8.5.2 | The organization must take action to eliminate the cause of nonconformities in order to prevent reoccurrence. Corrective actions must be appropriate to the nonconformities encountered. | ☐ | ☐ | ☐ | ☐ | | ~~ |

| Section | Requirement | Identified Assigned | Responsibility Assigned | Implemented Maintained | Effective | Notes | Min. Maj. CIP |
|---|---|---|---|---|---|---|---|
| 8.5.2.a | **A documented procedure must be established to define requirements for** reviewing nonconformities (including customer complaints). | ☐ | ☐ | ☐ | ☐ | | ~~ |
| 8.5.2.b | determining the causes of nonconformities. | ☐ | ☐ | ☐ | ☐ | | ~~ |
| 8.5.2.c | evaluating the need for action to ensure that nonconformities do not recur. | ☐ | ☐ | ☐ | ☐ | | ~~ |
| 8.5.2.d | determining and implementing action needed. | ☐ | ☐ | ☐ | ☐ | | ~~ |
| 8.5.2.e | records of the results of actions taken. | ☐ | ☐ | ☐ | ☐ | | ~~ |
| 8.5.2.f | reviewing corrective action taken. | ☐ | ☐ | ☐ | ☐ | | ~~ |
| **8.5.3 Preventive Action** | | | | | | | |
| 8.5.3 | The organization must determine action to eliminate causes of potential nonconformities in order to prevent their occurrence. Preventive actions must be appropriate to the effects of the potential problems. | ☐ | ☐ | ☐ | ☐ | | ~~ |
| 8.5.3.a | **A documented procedure must be established to define requirements for** determining potential nonconformities and their causes. | ☐ | ☐ | ☐ | ☐ | | ~~ |
| 8.5.3.b | (documented | ☐ | ☐ | ☐ | ☐ | | ~~ |

| Section | Requirement | Identified Assigned | Responsibility Assigned | Implemented Maintained | Effective | Notes | Min. Maj. CIP |
|---|---|---|---|---|---|---|---|
| | procedure) evaluating the need for action to prevent occurrence of nonconformities. | | | | | | |
| 8.5.3.c | determining and implementing action needed. | ☐ | ☐ | ☐ | ☐ | | ~~ |
| 8.5.3.d | records of results of action taken. | ☐ | ☐ | ☐ | ☐ | | ~~ |
| 8.5.3.e | reviewing preventive action taken. | ☐ | ☐ | ☐ | ☐ | | ~~ |
| Element 9: CONTROL OF THE USDA PROCESS VERIFIED TERM AND SHIELD | | | | | | | |
| **9.1 Use of Term and Shield** | | | | | | | |
| 9.1 | The organization may use the term “USDA Process Verified” and the USDA Process Verified Shield in promotional and advertising materials which include labels, packaging, websites, brochures, and other marketing materials. The organization must request use of the term and shield. | ☐ | ☐ | ☐ | ☐ | | ~~ |
| 9.1 a | **A documented procedure for the use of promotional materials must be established to**: Identify a person or persons with responsibility for the review, distribution and control of promotional materials; | ☐ | ☐ | ☐ | ☐ | | ~~ |

| Section | Requirement | Identified Assigned | Responsibility Assigned | Implemented Maintained | Effective | Notes | Min. Maj. CIP |
|---|---|---|---|---|---|---|---|
| 9.1 b | Ensure that the specified process verification points are accurately represented in the materials | ☐ | ☐ | ☐ | ☐ | | ~~ |
| 9.1 c | Ensure that the USDA Process Verified shield and the term "USDA Process Verified" are placed on product labels, promotional material, or advertising in a manner directly associated with a clear description of the specified process verification points. | ☐ | ☐ | ☐ | ☐ | | ~~ |
| 9.1 d | Ensure that the use of the term and shield are not misrepresented and are not used in association with any company claims | ☐ | ☐ | ☐ | ☐ | | ~~ |
| 9.1 e | Ensures that promotional materials reference the GIPSA Process Verified Program website, when possible. | | | | | | |
| 9.1 f | Provides for proper control and use of the term and shield on materials by<br><br>i) Ensuring that promotional materials are supplied to and used only by approved entities;<br><br>ii) Providing for a | ☐ | ☐ | ☐ | ☐ | | ~~ |

| Section | Requirement | Identified Assigned | Responsibility Assigned | Implemented Maintained | Effective | Notes | Min. Maj. CIP |
|---|---|---|---|---|---|---|---|
| | system of surveillance to prevent unauthorized use of process verification points, the term "USDA Process Verified" or the USDA Process Verified shield; and<br><br>iii) ensuring that materials are submitted to the Process Verified Program Manager for approval prior to use. | | | | | | |
| **9.2 Placement of the "USDA Process Verified" Term and Shield** | | | | | | | |
| 9.2 a | Placement of the USDA Process Verified Term and Shield must meet one fo the following conditions: the specified process verified points are printed immediately adjacent to the USDA Process Verified Shield | | | | | | |
| 9.2 b | An asterisk referring the consumer to the information panel for further information about the specified process verified points is printed with the USDA Process Verified Shield | | | | | | |
| 9.2 c | And asterisk referring the consumer to point of sale information is printed with the USDA Process Verified Shield. In this | | | | | | |

| Section | Requirement | Identified Assigned | Responsibility Assigned | Implemented Maintained | Effective | Notes | Min. Maj. CIP |
|---|---|---|---|---|---|---|---|
| | situation, the organization must ensure that the point of sale information is readily available and within close proximity of the display counter containing the product. | | | | | | |
| | | | | | | | |
| | | | | | | | |

| Audit Summary<br>Report of Closing Meeting | | | | | | | |
|---|---|---|---|---|---|---|---|
| | **Positives of Program:** | (list positive activities, behaviors, performance) | | | | | |
| | **Process Verified Points:** | (list Verification Points) | | | | | |
| | **Findings:** | (list the number of Major NCs, Minor NC, and CIPs) | | | | | |
| **# Major Non-conformance** | | | | | | | |
| | | ☒ | ☒ | ☐ | ☐ | | Maj |
| | | ☒ | ☒ | ☐ | ☐ | | Maj |
| **# Minor Non-conformances** | | | | | | | |
| | | ☒ | ☒ | ☐ | ☐ | | Min |
| | | ☒ | ☒ | ☐ | ☐ | | Min |
| | | ☒ | ☒ | ☐ | ☐ | | Min |
| **# Continuous Improvement Points** | | | | | | | |
| | | ☒ | ☒ | ☐ | ☐ | | CIP |
| | | ☒ | ☒ | ☐ | ☐ | | CIP |
| | | ☒ | ☒ | ☐ | ☐ | | CIP |
| | | ☒ | ☒ | ☐ | ☐ | | CIP |
| | | ☒ | ☒ | ☐ | ☐ | | CIP |
| | | ☐ | ☐ | ☐ | ☐ | | |

**CONCLUSION**: Based on the audit findings the audit team finds that the program (meets or does not fully meet) the requirements of the GIPSA Process Verified Program.

designates this audit report and all associated documents as proprietary information.

| Section | Requirement | Identified Assigned | Responsibility Assigned | Implemented Maintained | Effective | Notes | Min. Maj. CIP |
|---|---|---|---|---|---|---|---|

Signature Date